

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference P322A/PCT/JRW/Rs | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). | |
| International Application No. PCT/AU2003/001289 | International Filing Date (day/month/year) 30 September 2003 | Priority Date (day/month/year) 1 October 2002 |
| International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61B 1/317 | | |
| Applicant SPINEMED AUSTRALIA PTY LIMITED et al | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

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| Date of submission of the demand 27 April 2004 | Date of completion of the report 24 January 2005 |
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929 | Authorized Officer SWAYAM CHINTAMANI Telephone No. (02) 6283 2202 |

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-33, 51, 62-64 are directed to a system or method for imaging the interior of a bodily cavity having first and second imaging means, both positionable within the interior, the second means positionable relative to the first, wherein the first image depicts the location of the second imaging means. It is considered that the first image depicting the location of the second imaging means comprises the first special technical feature.

2. Claims 34-50, 52-61, 65-70 are directed to a system or method for mapping the interior of a bodily cavity comprising a position indication means variably positionable within, a position detection means for receiving a signal from the position indication means and a processor means that analyses said signal and provides output indicative of location of position indication means relative to position detection means. It is considered that the processor means that analyses the signal and provides output indicative of location of position indication means relative to position detection means comprises the second special technical feature.

Since these groups of claims do not share a special technical feature, they do not satisfy the requirement of unity of invention.

No additional search fees were paid to the International Searching Authority

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-33, 51, 62-64

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

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|-------------------------------|------------------------|-----|
| Novelty (N) | Claims 1-33, 51, 62-64 | YES |
| | Claims | NO |
| Inventive step (IS) | Claims 1-33, 51, 62-64 | YES |
| | Claims | NO |
| Industrial applicability (IA) | Claims 1-33, 51, 62-64 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 EP 0211783 (SOCIETE EN COMMADITE PAR ACTIONS DITE et al)
- D2 US 4916533 (GILLIES et al)
- D3 WO 1993/020742 (DANEK MEDICAL, INC.)
- D4 US 5381784 (ADAIR)
- D5 WO 1996/039916 (OKTAS GENERAL PARTNERSHIP)
- D6 DE 19800765 (SIEMENS AG)
- D7 US 6385476 (OSADCHY et al)

The present application defines a system method and device of imaging the interior of a body cavity characterised by a first imaging means depicting the location of the second imaging means and the second means is movable relative to the first means. Both imaging means are "positionable" within the interior of the body cavity.

Document D1 is directed to an endoscope with two cameras (5g, 5d) producing images of the same portion of an internal cavity in a patient. The object is to produce a stereoscopic image rather than one camera producing an image of the other. D2 provides an endoscopic imaging device with an illuminating lens (15) and an objective lens (16). The arrangement of imaging means defined in the claims considered is not suggested by these documents.

D3 discloses a system to allow direct visualisation of the epidural space. The tip of a catheter may be deflected to vary the viewing angle of the fibre-optic bundle in the catheter and steer the catheter through tight regions in the spinal space. D4 recites an imaging endoscope with one camera (82a) housed in the endoscope and a second (82b) in a tip portion connected to the endoscope by a hinge (76). D5 provides an endoscope with twin cameras in asymmetric position within the endoscope. The object is to provide two cameras without needing to enlarge the diameter of the catheter to accommodate two optical fibres. In document D6 a number of sensor elements (12) may be deployed around the inside of a body cavity. First and second imaging means as defined in the noted claims are not suggested by these documents.

Document D7 is the closest art and discloses a device for imaging the inside of a heart. A first image is obtained of the interior of the heart and a second image is superimposed over the first such that the position of a distal tip of the imaging catheter is indicated. A first imaging device depicting the location of a second imaging device is not suggested by this document

Claims 1 to 33, 51 and 62 to 64 satisfy Articles 33(2), 33(3) and 33(4) of the PCT since they are novel, and possess an inventive step in view of the cited prior art, and have an industrial application.